

REMARKS

Applicant respectfully requests reconsideration of this application in view of the following remarks and the Declaration of Dr. Masini-Eteve submitted herewith.

Applicant respectfully urges entry and consideration of the Declaration after final because it is believed to directly address the issues raised in the Office Action and place the application in condition for allowance or, at the very least, in better condition for appeal.

I. Status of the Claims

Claims 31-36, 38-39 and 43-48 remain pending and are not amended. These claims are presented for reconsideration.

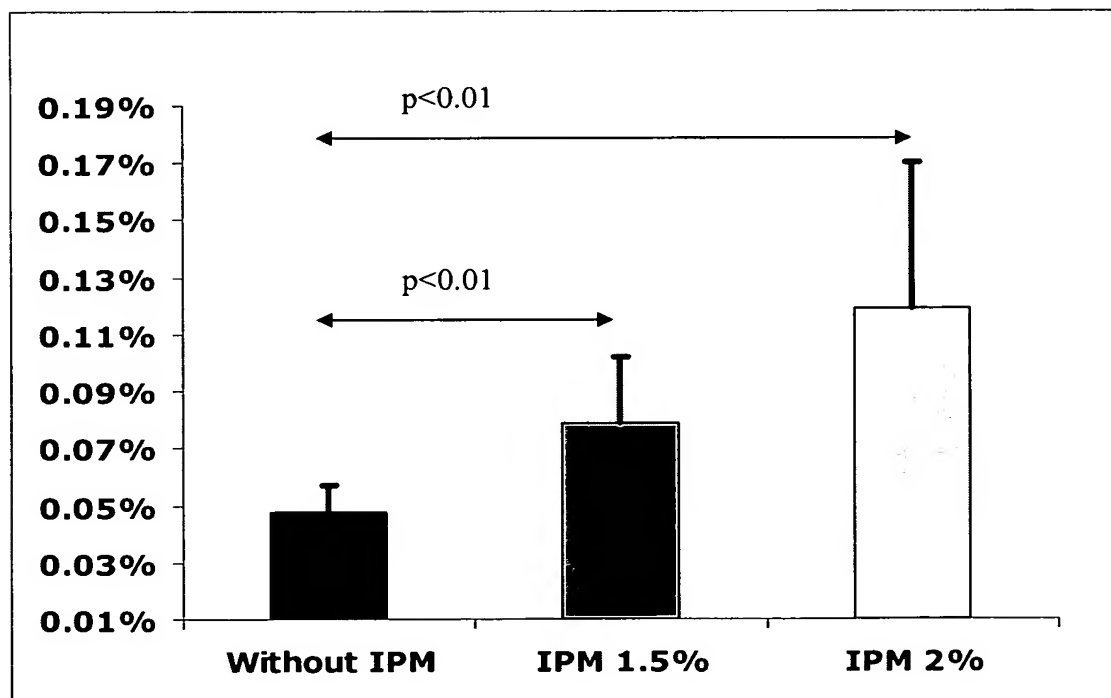
III. § 103 Rejections

The Office Action maintains the §103 rejections originally set forth in the March 13, 2007, Office Action, revised in view of intervening claim amendments: Claims 31-34, 36, 39, 43-45 and 47 stand rejected under 35 U.S.C. § 103(a) for alleged obviousness over Mauvais-Jarvis in view of Gunther. Claims 31-34, 36, 39, 43-45 and 47 stand rejected under 35 U.S.C. § 103(a) for alleged obviousness over Mauvais-Jarvis in view of Parab. Claims 35 and 46 stand rejected for alleged obviousness over those same references, further in view of U.S. Patent No. 5,720,963 (Smith). Claims 38 and 48 stand rejected for alleged obviousness over Mauvais-Jarvis and Gunther or Parab, further in view of U.S. Patent No. 6,013,270 (Hargraves). Applicant respectfully traverses these rejections.

As discussed in Applicant's response filed September 11, 2007, and in the November 14, 2007, Patent Office Interview, the premise behind the obviousness rejections—that the disclosure of the use of a fatty acid ester as a penetration enhancer in any percutaneous composition (e.g., Gunther or Parab) renders obvious the specific composition at issue—is not scientifically sound. That is because the ability of a particular penetration enhancer to be effective for a particular active agent in a particular formulation is unpredictable, and none of the cited references teach that isopropyl myristate would be an effective penetration enhancer for 4-hydroxy tamoxifen.

From the “Response to Arguments” at page 2 of the Action and the discussions during the November 14, 2007 Patent Office Interview, Applicant understands the rejections to have been overcome with respect to claims reciting up to 1% IPM, because Dr. Masini-Eteve’s Declaration submitted with the September 11, 2007 response shows that IPM is an effective penetration enhancer for 4-OHT at concentrations up to 1%. However, the Examiner has questioned whether IPM is an effective penetration enhancer for 4-OHT at concentrations greater than 1%, because data presented in Dr. Masini-Eteve’s Declaration seem to show a fall off in efficacy at 0.9%, albeit not a statistically insignificant one. To address this concern and demonstrate non-obviousness over the full scope of the pending claims, Applicant submits herewith an additional Declaration by Dr. Masini-Eteve demonstrating that IPM is an effective penetration enhancer at concentrations greater than 1%.

As explained in her Declaration, Dr. Masini-Eteve conducted or oversaw in vitro permeation experiments to assess the affect of IPM on 4-OHT penetration at concentrations of 0%, 1.5%, or 2.0% (all w/w) IPM. Masini-Eteve Declaration, ¶5. As set forth in ¶10 of her Declaration, the results were as follows:



As Dr. Masini-Eteve attests, "[t]he results show that the concentrations of IPM tested have a significant impact on penetration." Masini-Eteve Declaration, ¶11. "Thus, IPM is an effective penetration enhancer for 4-OHT when used at concentrations above 1.0%, including at 1.5% and 2.0%." Masini-Eteve Declaration, ¶11.

As Applicant now has made a showing that is fully commensurate with the scope of the pending claims, Applicant respectfully requests that the obviousness rejections be reconsidered and withdrawn.

CONCLUSION

Applicant believes that this application is condition for allowance, and an early indication to that effect is respectfully requested.

If there are any questions regarding this submission, or if any issue remains, the Examiner is invited to contact the undersigned directly in order to advance prosecution.

The Commissioner is authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of concurrently submitted papers, then Applicant petitions for such extension, under 37 CFR §1.136, and authorizes payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

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